RESPONSE TO FFICE ACTION
US.S.N.: 0 71.747

Filed: August 10, 1999

Docket No. 06171.105005 (NOV 1000)

## In the Claims

Please cancel claims 1-2, 4-6 and 11-12; amend claims 3 and 7-10 and add claims 13-34, as set out below.

(Once Amended) A method for the treatment or prophylaxis of a hepatitis B virus infection in a host comprising administering an effective amount of  $\beta$ -L-2'-deoxycytidine of the formula:

or pharmaceutically acceptable salt thereof.

(Once Amended) A method for the treatment or prophylaxis of a hepatitis B virus infection in a host comprising administering an effective amount of  $\beta$ -L-thymidine of the formula:

or pharmaceutically acceptable salt thereof.

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(Once Amended) A method for the treatment or prophylaxis of a hepatitis B virus infection in a host comprising administering an effective amount of a combination of the following nucleosides:

1860

HO 
$$\frac{NH_2}{N}$$
  $\frac{NH_2}{N}$   $\frac{NH_3C}{N}$   $\frac{NH}{N}$   $\frac{NH}{N}$ 

or a pharmaceutically acceptable salt thereof.

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(Once Amended) A method for the treatment or prophylaxis of a hepatitis B virus infection in a host comprising administering an effective amount of a compound of the formula:

270561 COALD

or its pharmaceutically acceptable salt thereof, in combination or alternation with an effective amount of a compound selected from the group consisting of β-L-2-hydroxymethyl-5-(cytosin-1-yl)-1,3-oxathiolane (3TC), *cis*-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane (FTC), β-L-2'-fluoro-5-methyl-arabinofuranolyl-vuridine (L-FMAU), β-D-2,6-diaminopurine dioxolane (DAPD), famciclovir, penciclovir, 2-amino-1,9-dihydro-9-[4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]-6H-purin-6-one (entecavir, BMS-200475), 9-[2-(phosphono-methoxy)ethyl]adenine (PMEA, adefovir, dipivoxil); lobucavir, ganciclovir and ribavirin.

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A method for the treatment or prophylaxis of a hepatitis B virus (Once Amended) infection in a host comprising administering an effective amount of a compound of the formula:

or its pharmaceutically acceptable salt thereof, in combination or alternation with an effective amount of a compound selected from the group consisting of β-L-2cis-2-hydroxymethyl-5-(5hydroxymethyl-5-(cytosin-1-yl)-1,3-oxathiolané (3TC), fluorocytosin-1-yl)-1,3-oxathiolane (FTC), β-L-2'-fluoro-5-methyl-arabinofuranolyluridine (L-FMAU), β-D-2,6-diaminopurine dioxolane (DAPD), famciclovir, penciclovir, 2-amino-1,9-dihydro-9-[4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]-6Hpurin-6-one (entecavir, BMS-200475), 9-[2-(phosphono-methoxy)ethyl]adenine (PMEA, adefovir, dipivoxil); lobucavir, ganciclovir and ribavirin.

(New) The method of claim 3, wherein the β-L-2'-deoxycytidine is at least 95% in its designated enantiomeric form.

(New) The method of claim 2, wherein the β-L-2'-deoxycytidine is administered in a pharmaceutically acceptable carrier.

(New) The method of claim 14, wherein the pharmaceutically acceptable carrier is suitable for oral delivery.

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(New) The method of claim 14, wherein the pharmaceutically acceptable carrier is suitable for intravenous delivery.

(New) The method of claim 14, wherein the pharmaceutically acceptable carrier is suitable for parenteral delivery.

(New) The method of claim 14, wherein the pharmaceutically acceptable carrier is suitable for intradermal delivery.

(New) The method of claim 14, wherein the pharmaceutically acceptable carrier is suitable for subcutaneous delivery.

(New) The method of claim 14, wherein the pharmaceutically acceptable carrier is suitable for topical delivery.

(New) The method of claim 4, wherein the compound is in the form of a dosage unit.

(New) The method of claim 21, wherein the dosage unit contains 10 to 1500 mg of the compound.

(New) The method of claim 21 or 22, wherein the dosage unit is a tablet or capsule.

(New) The method of claim 7, wherein the  $\beta$ -L-thymidine is at least 95% in its designated enantiomeric form.

(New) The method of claim  $\frac{\mathcal{D}}{\mathcal{I}}$ , wherein the  $\beta$ -L-thymidine is administered in a pharmaceutically acceptable carrier.